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J. Timothy Keane
Harness, Dickey & Pierce, PLC
7700 Bonhomme Avenue, Suite 400
Clayton, MO 63105

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,884,434

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,884,434, claims of which cover the human drug product NEUPRO® Transdermal System, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 743 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 743 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of (). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2}(\text{TP} - \text{PGTP})^1 \\ &= 4,367 - 3,624 - 0 - \frac{1}{2}(2,379 - 2,379 \text{ days}) \\ &= 743 \text{ days (2.0 years)}\end{aligned}$$

Since the regulatory review period began May 27, 1995, before the patent issued (April 26, 2005), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 27, 1995, to and including, April 26, 2005, is 3,624 days; this period is subtracted from the number of days occurring in the regulatory review period according to the FDA determination of the length of the regulatory review period which occurred on and before the patent grant date.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

¹ Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of $\frac{1}{2}(\text{TP} - \text{PGTP})$. See 37 C.F.R. § 1.775(d)(1)(iii).

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,884,434
Granted:	April 26, 2005
Original Expiration Date ² :	March 18, 2019
Applicant:	Walter Muller et al.
Owner of Record:	LTS Lohmann Therapie-Systeme AG and UCB Pharma GMBH
Title:	Transdermal Therapeutic System Which Contains a D2 Agonist and Which is Provided for Treating Parkinsonism and a Method for the Production Thereof
Product Trade Name:	NEUPRO® Transdermal System
Term Extended:	743 days
Expiration Date of Extension:	April 26, 2022

²Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy RE: NEUPRO® Transdermal
Food and Drug Administration System
10903 New Hampshire Ave., Bldg. 51, Rm. 6222 Docket No.: 2007E-0445
Silver Spring, MD 20993-0002

Attention: Beverly Friedman